

68-9-2. Automated drug delivery systems in pharmacies. (a) For purposes of this regulation, “automated drug delivery system” shall ~~include any~~ mean a robotic, mechanical system, or computerized device located in a Kansas pharmacy that performs operations or activities other than compounding or administration, ~~relative to~~ involving the storage, packaging, or labeling of or any other step before dispensing, ~~or distribution of drugs, in situations in which the drug is not reviewed by a Kansas-licensed pharmacist after it leaves the mechanical system and before it is dispensed, distributed, or administered.~~ Each prescription medication prepared by an automated drug delivery system shall be verified and documented by a Kansas-licensed pharmacist as part of the dispensing process.

(b) A pharmacist-in-charge of any licensed pharmacy, licensed health care facility, or other location that is required to be supervised by a pharmacist-in-charge and that uses an automated drug delivery system shall ~~be responsible to take~~ perform the following steps before allowing the automated drug delivery system to be used:

(1) Ensure that the automated drug delivery system is in good working order and accurately ~~dispenses~~ selects the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(2) ensure that the automated ~~pharmacy~~ drug delivery system has a mechanism for securing and accounting for all drugs removed from and subsequently returned to the system;

(3) ensure that the automated ~~pharmacy~~ drug delivery system has a mechanism for securing and accounting for all wasted or discarded drugs;

(4) ~~implement a documented and~~ ensure compliance with an ongoing continuous quality assurance improvement program pursuant to K.S.A. 65-1695, and amendments thereto, or a risk management program that monitors total system performance and includes the requirement for accuracy in the drug and strength delivered;

(5) ensure that the automated drug delivery system is ~~stocked~~ loaded accurately and according to ~~established and written policies and procedures~~ the original manufacturer's storage requirements;

~~(6) ensure that the use of the automated drug delivery system maintains patient confidentiality;~~

~~(7)(6)~~ approve and implement an operational policy that limits the personnel responsible for the loading and unloading of drugs to or from the automated drug delivery system to ~~a Kansas-licensed pharmacist or to any of the following, each of whom shall be under the pharmacist's direct supervision:~~

(A) ~~A pharmacy student~~ Kansas-licensed pharmacist;

(B) a Kansas-registered pharmacy intern; or

(C) a Kansas-registered pharmacy technician;

(7) at the location of the automated drug delivery system, maintain a current list of those approved individuals who are authorized to unload any drug from the automated drug delivery system;

(8) approve and implement security measures that ~~comply with~~ meet the requirements of all applicable state and federal laws and regulations in order to prevent unauthorized individuals from accessing or obtaining drugs;

(9) preapprove all individuals who are authorized to ~~remove~~ unload any drug ~~and maintain, at the location of~~ from the automated drug delivery system, ~~a list of those approved individuals;~~

(10) ~~ensure the accuracy of the automated drug delivery system's collection, control, and maintenance of all transaction information needed to track the movement of drugs into and out of the system for security, accuracy, and accountability; and~~ ensure that all drugs loaded in the automated drug delivery system are packaged in the manufacturer's sealed original packaging or in repackaged containers, in compliance with K.A.R. 68-7-15 and K.A.R. 68-7-16;

(11) provide the board with prior written notice of the installation or removal of the automated

drug delivery system; and

(12) ensure that a system of preventive maintenance and sanitation for the automated drug delivery system is established and followed.

~~(c) A pharmacist in charge of any licensed pharmacy, licensed health care facility, or other location that is required to be supervised by a pharmacist in charge and that uses an automated drug delivery system shall be responsible to ensure all of the following:~~

~~(1) The drugs within the automated drug delivery system are inspected on-site by a Kansas-licensed pharmacist or by any of the following, each of whom shall be under the pharmacist's direct supervision:~~

~~(A) A pharmacy student;~~

~~(B) a pharmacy intern; or~~

~~(C) a pharmacy technician. These inspections shall be conducted at least monthly to ensure accuracy of contents.~~

~~(2) All drugs placed within the device are packaged in the manufacturer's sealed original packaging or in repackaged containers, in compliance with the requirements of K.A.R. 68-7-15 and K.A.R. 68-7-16. However, the dispensing container shall not be required to be labeled as specified in K.A.R. 68-7-14 if the dispensing container is utilized for a registered patient of the licensed health care facility and for immediate administration.~~

~~(3) At the time of loading any controlled substance, the count of that drug in the automated drug delivery system is correct, or any discrepancy is immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or proper reporting of the loss. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1626, as amended by L. 2002, ch. 25, sec. 2~~

K.S.A. 2015 Supp. 65-1637 and 65-1642; effective July 6, 2001; amended Feb. 7, 2003; amended P-

_____.)